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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,416	11/30/2001	David M. Hodgson	PT-1042 USN	1524

27904 7590 04/22/2003

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EXAMINER
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ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,416	HODGSON ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,9,10,12,13,15-17,19,20 and 57-63* is/are pending in the application.

4a) Of the above claim(s) *13,15,19,20 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,9,10,12,16,17 and 58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *0203* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed February 24, 2003. Currently, claims 1, 4-6, 9-10, 12-13, 15-17, 19-20, 57-63 are pending. Claims 13, 15, 19-20, 57 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election with traverse of Group I (Claims 1, 4-6, 9-10, 12, 16-17, 58-63) is acknowledged.

The response traverses the lack of unity.

First, newly added Claim 57 appears to most closely correspond to Claim 21 (Group VII). Therefore, Claim 57 does not belong in Group I as suggested by applicants.

Applicant argues that Claim 2 and 13 share unity of invention. The response relies upon Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted as between claims to polypeptide sequences and claims to polynucleotide sequences encoding those polypeptides. This argument has been reviewed, but is not persusassive because the example does not provide that any nucleic acid and polypeptide share unity of invention. The example is drawn to a very specific example which recites Claim 1: Protein X and Claim 2: DNA sequence encoding protein X. First, the instant application differs in that Claim 1 is drawn, in part, to a nucleic acid having at least 90% identity to a polynucleotides consisting of SEQ ID NO: 4. The example is not drawn to percent homology language. A claim drawn to homology language will encompass numerous proteins rather than a

single protein as exemplified in the examples. The MPEP does not contemplate examining more than one protein in a single application. Second, in the example, Claim 1 is drawn to a protein and Claim 2 is drawn to a nucleic acid encoding the protein. However, in the instant case, Claim 1 is drawn to a nucleic acid and Claim 2 is drawn to a protein encoded by Claim 1. Finally, as another distinguishing feature between the claims in the instant case and the claims in the example is that the claims in the example are not written in dependant form. Therefore, the instant case is clearly distinguishable from the narrow example provided in Annex B.

The response also argues that Unitv of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend. This argument has been thoroughly reviewed, but found unpersuasive because original Group I was directed to Claims 1-10, 12, 16-17, 22-28, 43-56. The group now comprises 1, 4-6, 9-10, 12, 16-17, 58-63. Therefore, it is unclear to the examiner applicant's arguments with respect to the dependencies. Claims 2-3, 7-8, 11, 14, 18 have been cancelled therefore, the arguments with respect to these claims is moot. Moreover, are discussed above, Claim 1 and 13 lack a special technical feature.

The applicant's arguments with respect to the burden is moot because lack of unity requirements do not require the proof of burden. However, the search of each of these groups is not coextensive of each other.

With respect to the further restriction requirement to a single sequence, the response argues that the members are sufficiently few in number and are closely related. Neither of these assertions is deemed by the examiner to apply to the instant

application. The claim is directed to 14 specific sequences and further to additional sequences with 90% homology. Moreover, the sequences are not closely related in any meaningful way. Additionally, the response asserts that unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case the instant sequences fail to share a common utility. The response asserts that the compounds are classified as human transport proteins and transmembrane domains. This argument has been thoroughly reviewed, but not found persuasive because the instant specification fails to describe these nucleic acids as either human transport proteins or any particular transmembrane domains. The compounds are not all directed to the same disease detection, directed to the same expression pattern etc. Furthermore, there is no common structure between all of the nucleic acids (i.e. a conserved region, a domain, etc). Therefore, the Markush group is not directed to a common utility or common structural feature.

With respect to 803.04 directed to nucleotide sequence claims, the MPEP clearly states that the maximum number of independent and distinct nucleotides sequences examined would be 10. However, the MPEP also provides clearly, that "nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Should applicant traverse on the

ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Applicant's remarks directed to combination claims is moot as none of the instant claims are drawn to a claim requiring a particular combination of sequences.

This application contains claims 13, 15, 19-20, 57 drawn to an invention nonelected with traverse in the response filed February 24, 2003 A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. This application claims priority as a 371 to PCT US00/15344 filed June 1, 2000 and provisional applications 60/137,412, 60147,500, 60/147,501, 60/147,542.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 119 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

New Matter

4. Claims 58-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "polynucleotide sequences specifically hybridizable with at least 30 contiguous nucleotides" distinct physical location on the substrate contains multiple nucleotide molecules having the same sequence, and each distinct physical location on the substrate contains nucleotide molecules having a sequence which differs from the sequence of nucleotide molecules at another physical location on the substrate" are included. The amendment proposes that the new claim language clarifies the issue can be found on page 8, 11, 24. Upon review of these pages, the examiner has not found any support for these limitations. The concept of "polynucleotide sequences specifically hybridizable with at least 30 contiguous nucleotides" distinct physical location on the substrate contains multiple nucleotide molecules having the same sequence, and each distinct physical location on the substrate contains nucleotide molecules having a sequence which differs from the sequence of nucleotide molecules at another physical location on the substrate" does not appear to be part of the originally filed invention. Therefore, these recitations constitutes new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 4-6, 9-10, 12, 16-17, 58-63 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims drawn to polynucleotides, and method of detecting the polynucleotides as defined in the specification as disease detection and treatment molecule polynucleotides (MDDT).

The specification teaches the general utility for the invention is for the detection, microarray detection, toxicology testing and screening compounds (page 22). The specification also asserts MDDT may used for a variety of diagnostic and therapeutic purposes (page 22). These diagnostics and therapeutic uses are in the form of a laundry list of diseases which are unrelated and distinct. The diagnosis, treatment or prevention of diseases ranges from any proliferative cellular disorders to any autoimmune/inflammatory disorder (pg. 22). As seen in Table 2, SEQ ID NO: 4 is similar to an "uncharacterized protein family." Therefore, the specification has not assigned the nucleic acid to any particular family.

The specification does not teach a specific utility of the polynucleotide, i.e. SEQ ID NO: 4, whereby the invention would be a useful tool for a specific purpose i.e.

detection of itself in a sample detects the presence of a specific disease. The specification does not teach the disease which is associated with decreased expression or activity of MDDT. The specification does not teach the therapy or demonstrate therapeutic results. The specification has provided no "real world" use for the polynucleotide that would constitute a substantial utility.

Each of the asserted utilities have been separately analyzed. A well-established utility is defined as a specific, substantial and credible utility which is well known, immediately apparent or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. For a utility to be a specific utility, the utility must be *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. Additionally, utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

In considering toxicology testing. the particulars of toxicology testing with SEQ ID NO:4 are not disclosed in the instant specification. Neither the toxic substances nor the susceptible organ systems are identified. Therefore, this is a utility which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA. This utility is not specific with respect to SEQ ID NO:4. Moreover, use of the claimed polynucleotide in an array for toxicology screening is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array. Again, this is a utility which would apply to virtually ever member of a general class of

materials, such as any collection of proteins or DNA. The specification does not disclose the significance of any test results, nor is there any evidence that the significance was known as of the filing date. If the expression of the claimed polynucleotide increases, is this a positive or negative outcome? Would this be a toxic response or not? The disclosure is insufficient to evaluate the results of the test in any meaningful manner such that the claimed polynucleotides have a specific, substantial or well-established utility.. Even if the expression of the individual polynucleotide of SEQ ID NO: 4 is affected by a test compound in an array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information regarding this nucleic acid could be put. Therefore, the use of arrays for toxicological testing lacks a specific and substantial utility.

With regard to diagnosis of disease, the specification asserts that expression profiling is used to identify drug targets and characterize disease (see page 22). Because any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. However, in order for a polynucleotide to be useful, as asserted, for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. The specification has not associated SEQ ID NO: 4 with cancer or cell proliferation, inflammation, and trauma. The knowledge that a polynucleotide is expressed in a range of tissues does not

provide any utility for the polynucleotide. Similarly, the knowledge that the polynucleotide is found in cancer and cell proliferative cells and such does not provide utility, since numerous genes are found in both normal and diseased cells, i.e. housekeeping genes. These pieces of knowledge do not provide any utility to the claimed polynucleotides. The presence of a polynucleotide in tissue that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of

use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Specific utility must be shown or be evident for each member of the class. None of the utilities identified by Appellants, i.e. toxicology testing, drug discovery, disease diagnosis, have been demonstrated to be specific to SEQ ID NO:4. One of ordinary skill in the art must understand how to achieve an immediate and practical benefit from the claimed species based on the knowledge of the class. However, no practical benefit has been shown for the use of SEQ ID NO:4. Therefore, the specification does not teach a specific or substantial utility for the invention such that the invention would be useful to detect or treat a specific disease state. Therefore, since the specification fails to provide a specific or substantial utility for SEQ ID NO: 4, the credibility test has not been analyzed.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 4-6, 9-10, 12, 16-17, 58-63 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Additionally, the claims are broadly drawn to a method of detecting a target polynucleotide by hybridizing the sample with a probe comprising at least 20 contiguous nucleotides comprising a sequence complementary to the target polynucleotide. The claims are also drawn to an array with at least 30 contiguous nucleotides of a target polynucleotide.

The art teaches a variety of sequences which contain more than 30 contiguous nucleotides which appear to be distinct from SEQ ID NO: 4. Therefore, a probes which is 30 contiguous nucleotides will detect target nucleotides which are not SEQ ID NO: 4 nor are specific for SEQ ID NO: 4. For example, Genbank Accession Number ABK86000 is directed to a human cDNA encoding bipolar affective disorder-related protein which comprises more than 30 contiguous nucleotides from SEQ ID NO: 4. As seen in the alignment, the nucleic acids have a local similarity of 98.5% over 1420 nucleotides. Additionally, Genbank Accession Number ABV36882 is directed to human prostate expression marker cDNA which has a local similarity with SE QID NO: 4 of 97.0% over approximately 430 nucleotides. Therefore, places these nucleotides which comprises at least 30 contiguous nucleotides would detect both the bipolar and prostate sequences in addition to the claimed SEQ ID NO: 4. Therefore, detecting only a small portion of SEQ ID NO: 4 either by amplification or by probes will not detect the target polynucleotide exclusively. Therefore, the skilled artisan would be required to perform additional experimentation to determine whether the detected hybridization complex is the target polynucleotide of SEQ ID NO: 4.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4-6, 9-10, 12, 16-17, 58-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to an isolated polynucleotide comprising a naturally occurring polynucleotide sequence having at least 90% sequence identity to SEQ ID NO: 4. SEQ ID NO: 4 is 2059 nucleotides in length. Therefore for a nucleic acid of the same length, the nucleic acid may differ by as many as 205 nucleotides and still be within the scope of the claims.

It is well established that to claim a chemical compound, such as a polynucleotide, the inventor must be able to define the compound so as to distinguish the compound from other materials. The claimed compound must be defined in terms so as to provide a permanent and definite idea of the complete and operative invention. In the instant case, the claimed polynucleotides have not been clearly defined in terms of structure and/or function, and therefore one cannot make and use the polynucleotides as claimed. As stated in Vaek (CAFC 20 USPQ2d 1438, the "specification must teach those of skill in the art how to make and use the invention as

broadly as it is claimed." However, in order to be able to make an invention, one must be able to clearly define that invention.

The specification teaches a single nucleic acid within the scope of the claims, namely the nucleic acid consisting of SEQ ID NO: 4. There is actual reduction to practice of the single disclosed species of SEQ ID NO: 4.

Based upon the specification it is unclear whether the nucleic acid of SEQ ID NO: 4 is a cDNA, a partial cDNA, a nucleic acid which contains exon/intron splice junctions. The claim is drawn to a genus, i.e., any nucleic acid that minimally contains SEQ ID NO: 4 within it including full length genes which contains the sequence. The disclosure of a single disclosed species, in this case, is not representative of the genus. The present claims encompass full-length genes and cDNAs that are not described. The claim also encompasses splice variants, homologs, truncations among other sequences. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 4 is only a fragment of any full-length gene or cDNA species.

With respect to the percent identify limitations in the claim, the Written Description Guidelines provide an analogous example, namely Example 14. Unlike Example 14, the instant claims do not provide any particular function for the nucleic acid. Neither the specification nor the claims set forth any particular structural or functional characteristics required by the claims. As discussed above, the claims is broadly drawn to encompass allelic variants, homologs and splice variants. The general knowledge in the art concerning alleles does not provide any indication of how the

structure of one allele is representative of unknown alleles. The nature of alleles is such that variant structures, and in the present stat of the art the structure of one alleles does not provide guidance to the structure of others. Moreover, it is established that alleles may differ functionally according to their distinct structures. Alleles may differ in the amount of biological activity, may differ in the amount of protein produces and may even differ in the kind of activity. Therefore, the description of a single sequence is not representative of all alleles and variants within the scope of 90%.

Moreover, it is unclear from the specification which of the nucleic acids which are 90% identical with SEQ ID NO; 4 are "naturally occurring" as required by the claims. The specification has described only a single naturally occurring nucleic acid.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO: 4, 2) the breadth of the claim as reading on genes yet to be discovered in addition to cDNAs, 3) lack of correlation between the structure and the function of the genes; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise SEQ ID NO: 4.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 6, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 6 is indefinite because it is unclear as to whether the claims are intended to be limited to methods of detecting a target polynucleotide in a sample or detecting the presence or absence of a hybridization complex. The claims are drawn to a method of detecting a target polynucleotide but the final process step is detecting the presence or absence of a hybridization complex. Accordingly it is unclear as whether the claimed method is one for detecting a target polynucleotide in a sample or detecting the presence or absence of a hybridization complex.

B) Claim 17 is indefinite because it is unclear as to whether the claims are intended to be limited to methods of generating a transcript image or quantifying the expression of the polynucleotides in the sample. In Claim 17 it is unclear whether the method is for generating a transcript image of a sample or quantifying the expression of the polynculeotdies in the sample. Additionally, "the elements of the microarray" in claim 17 lack proper antecedent basis because Claim 16 relies upon at least one element rather than elements more broadly. Therefore, it is not required that Claim 16 contain multiple elements. Therefore, as written "the elements" lacks antecedent basis.

Conclusion

9. No claims allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is

(703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
April 17, 2003

Gary Benzion

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